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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,761	11/06/2001	Peter F. Searle	CACO-0067(P21303US)	9242

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COZEN O'CONNOR, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,761	SEARLE, PETER F.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/28/04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

DETAILED ACTION

Election/Restrictions

Applicant's election on 12/28/04 of the following species (a) kanamycin resistance;(b) nitroreductase (more specifically nfnB1;(c) CB1954; (d) nitroreductase (more specifically nfnB) is noted. Applicants state that all elected claims, claims 1-17, read on the elected species. [This restriction/election of species is made in view of applicants' request or clarification in the REMARKS that there is no record as to this species election.]

Status of Claims

Claims 1-21 are pending

Claims 18-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-17 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action (3/23/04).

Response to Arguments

Applicants argue that the method does not use any type of prodrug but, rather, prodrugs that activate the proteolytic activity of bacterial RecA. Applicants further argue that the citation to Fischetti et al. seems misplaced. The cited passage of Fischetti et al., i.e., column 2, lines 1-14, is not directed to phage libraries but, rather, the use of bacteriophage to treat bacterial infections.

In response, the detailed description in the specification, relates to a single prodrug that activate a single bacterial RecA with a bacteriophage containing a nucleotide encoding a single enzyme derived from a fragment of the bacterial gene. It does not correlate this single prodrug, CB1954 to any type of prodrug with the function of proteolytically cleaving any type of bacterial RecA. The specification defines a prodrug in such generic and vague terms. Prodrug is defined as any drug molecule that is itself relatively inert pharmaceutically but which has a

pharmacological effect once activated in an organism by biological, biochemical, chemical or physical means. This encompasses a huge scope of any prodrug activated by any means in any kind of bacterial organism to result in any type of pharmacological effect of the drug. It does not give the full scope encompassed by the prodrug in specific terms as by its structure, figures and formulas that fully set forth the claimed genus to show possession of the claimed genus. A genus, like a species, is complete when the genus used in the method is described with all of its limitations using such descriptive terms, as above-mentioned. Or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the huge scope of the claimed invention. Page 11, lines 13-29 of the instant specification list a few of these prodrugs. It does not describe in details the function of these prodrugs in proteolysis of bacteria RecA as applied to other bacteria besides E. coli. A laundry list disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species). In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967). The claims recite for numerous undefined variables that one cannot readily envisaged possession of the genus

containing such huge scope based on the described single species for each of the undefined variables.

Fischetti, albeit drawn to a single bacteriophage rather than a library of bacteriophage, clearly demonstrates that even for a single bacteriophage (not a library), one cannot predict the action of a species to a genus. Fischetti describes that phage lytic enzymes specific for bacteria infected with a specific phage can effectively and efficiently break down the cell wall of the bacterium in question. Fischetti describes the drawbacks in the used of a single bacteriophage, albeit for treatment method, although would appear applicable for any bacteria and phage interaction. Fischetti discloses that the bacteria must be in the right growth phase for the phage to attach. Both the bacteria and the phage have to be in the correct and synchronized growth cycles. Additionally, there must be the right number of phages to attach to the bacteria; if there are too many or too few phages, there will either be no attachment or no production of the lysing enzyme. The phage must also be active enough. Adequate disclosure requires representative examples, which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that applicant had possession of the full scope of

the claimed invention. See In re Riat (CCPA 1964) 327 F2d 685, 140 USPQ 471.[See also the CAFC decision in the University of California vs. Eli Lilly and Co. CAFC 43 USPQ2d 1398 7/22/1997 with respect to adequate disclosure.] The more unpredictable the art the greater the showing required e.g. by representative examples for an adequate disclosure. (See e.g., paragraph bridging pages 8 and 9 and page 19, lines 7-18 of the specification, which discloses some of these unpredictable effects.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNeish (Gene Therapy) in view of Murray (Phages) for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that McNeish reports on treatment of ovarian and pancreatic cancer using nitroreductase, and the generation of pooled populations of non-bacterial cell lines. Murray reports on the construction and screening of phage libraries; it does not disclose or suggest the screening from phage-transformed bacteria as presently claimed.

In response, McNeish discloses the correlation of the expression of the E.coli nitroreductase (NTR)in tumor cells that activate the prodrug CB1954 to the treatment of cancer cells. While McNeish does not describe bacterial host cell, as argued however, Murray describes bacterial host cell. The combined teachings of the art have shown that either host cell has been known to be employed in the art. It would be within the ordinary skill in the art to pick or choose the host cells that would suit its purpose. In the absence of new and unexpected result in the use of bacterial host cell, the claimed invention is prima facie obvious.

Withdrawn Rejections

The 35 USC 112, second paragraph and 32 USC 102 and 35 USC 103 rejections under Maruyama are withdrawn in view of applicants' arguments.

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 18-21 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on(571) 272-0812. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
March 22, 2004